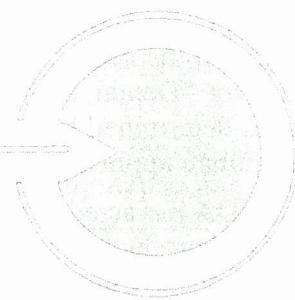


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FDA RULES AGAINST SAFETY OF MERCURY!

The United States Food and Drug Administration (FDA) has ruled that mercury and its compounds are NOT "Generally Recognized As Safe" (GRAS), and are eliminated from products sold "Over The Counter" (OTC). [FR 63(77):19799-19802, 22 April 1998.]

FDA ruled that mercury and its compounds must be removed from OTC products by 22 October 1998. Specifically listed in the rule were mercury and 15 of its compounds, including thimerosal and mercurochrome. FDA had previously ruled that mercury and all of its compounds be placed in Drug Category II for topical antimicrobial use. [FR47:436, 5 January 1982]

FDA further stated (p. 19801): "Any drug product containing any of these ingredients and labeled for the OTC use identified in Table II of this document will be considered nonmonograph and misbranded

under section 502 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 352]"; and (p. 19801), "Safety and effectiveness have not been established for the ingredients included in this current final rule and manufacturers have not submitted the necessary data in response to earlier opportunities." The uses identified in Table II (p. 19800) are: 1) First aid antiseptic drug products; 2) Vaginal contraceptive drug products; and 3) Antimicrobial diaper rash drug products.

The impact of this ruling by the FDA cannot, and should not, be under emphasized! First, the FDA has categorized mercury and its compounds as "drugs", whereas the FDA Dental Division has classified mercury as a "dental device." This FDA ruling determined that the manufacturers have NOT established the safety of mercury and its compounds, while the FDA Dental Division maintains its ruling that "Dental Mercury" is a safe and effective Class I Dental Device. [Ed Note: FDA Dental Division has still refused to consider mixed dental amalgam as a Dental Device. Instead, it holds to its previous ruling that "Dental Mercury" and "Amalgam Alloy" separately are safe and effective Dental Devices!]

In view of the persistent position of the Dental Division, it is apparent that the FDA has ruled that all forms of mercury are not acceptable for use anywhere on or in humans, except in the mouth! FDA provides no information or explanation as to why dental mercury is any different from any other mercury. In essence, then, the FDA position is that dental mercury is the only non-toxic form of mercury in existence, without supplying explanation or data to support the position! While determining that "manufacturers have not submitted the necessary data" to establish the safety of mercury and its compounds, the Dental Division of FDA has ac-

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cepted "Dental Mercury" as a safe and effective device in Class I, which does NOT require data on safety from the manufacturers. Nor does FDA explain why "Dental Mercury" is not considered a drug, as determined by their own regulation for the other human applications of mercury.

The FDA has acted strongly to protect consumers from OTC products containing mercury, but refuses to even consider protecting consumers from dental mercury, even though scientific documentation has clearly established a continuous exposure to mercury from amalgam dental fillings, as well as the transfer of amalgam mercury into body tissues. If anything, consumer exposure to dental amalgam mercury is far more extensive than mercury exposure from OTC products.

Since the Dental Division of FDA refuses to reconsider the safety of "Dental Mercury" and submit it to the same standards that the rest of FDA has for the other uses of mercury and its compounds, the only avenue is for members of the United States Congress to question the FDA for this dichotomy. FDA should be required to explain why mercury is unacceptable for use anywhere in the body except the mouth, what miraculous event occurs that renders "Dental Mercury" to be the only non-toxic form of mercury, why "Dental Mercury" is the only use of the substance that does not qualify it as a "drug" (and therefore applicable to those standards), and why the Dental Division of FDA refuses to submit "Dental Mercury" to the same investigative standards used for mercury by the rest of FDA!

NORWAY ON AMALGAM

Yet another country has taken steps to reduce the use of mercury dental fillings. We are grateful to Maryanne Rygg of Norway for providing the following information: The Norwegian Board of Health issued its recommendations at a press conference on 28 October 1998. The Health Board stated that while damage to health due to mercury from amalgam fillings has not been shown by clinical scientific methods, risk assessments have shown the probability that a minority of the population can develop health damage! In view of this, the Board issued recommendations against the use of dental amalgam in several circumstances:

1) Amalgam will not be the first choice of dental material for children under age 18.

2) Pregnant women (all comprehensive dental work discouraged).

3) Persons with special health problems, such as allergy or kidney disease.

Heavy emphasis was placed on the professional obligation to provide adequate information to the patients and obtain proper informed consent. The Board of Health recommended against the routine removal of functional amalgams, but that existing guidelines on dental bio-materials should be revised, including development of protocols to address symptoms that may be related to dental materials. They also recommended the development of guidelines to address occupational exposure in the dental office, focusing on education in the dental schools.

These recommendations will now be considered by the Ministry of Social Affairs and Health before being sent to the Norwegian Parliament. Norway has now been added to the growing list of governments who have issued formal advisories against the use of mercury amalgam dental fillings in some circumstances. These countries now number: Austria, Canada, France, Germany, Sweden, the United Kingdom, and possibly Denmark (unconfirmed) and Finland (unconfirmed).

DENTAL BOARDS AND MERCURY-FREE DENTISTRY

What is the role of mercury-free dentistry in the spectrum of health care? The answer to the question can be summarized, in order of precedence, as: 1) The position of organized dentistry in determining the "standard of care" for the profession; 2) the actions of the State Dental Boards; and 3) the status of valid scientific documentation.

It is extremely sad that valid scientific documentation is subservient to the dictates of organized dentistry. Scientifically, it is firmly established that: 1) Mercury continuously escapes from in situ amalgam dental fillings; 2) the released amalgam mercury enters the body and accumulates in the tissues of patients with amalgam fillings, and is the most predominant non-occupational source of mercury in humans; 3) mercury toxicology experts take the position that a toxic threshold for human exposure to mercury vapor has never been detected; and 4) formal risk assessments by the governments of the United States and Canada both concluded that